

EXHIBIT C

Gynecare[®] PROLIFTTM

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Totalt reparationssystem til bækkenbunden
Reparationssystem til anteriore bækkenbund
Reparationssystem til posteriore bækkenbund

Bekkenbodemreparatiesysteem totaal
Bekkenbodemreparatiesysteem anterieur
Bekkenbodemreparatiesysteem posterieur

Totaalinen lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système de reconstruction totale du plancher pelvien
Système de reconstruction antérieure du plancher pelvien
Système de reconstruction postérieure du plancher pelvien

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους



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ENGLISH



Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT™ Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training. Physicians should have experience in management of complications resulting from procedures using surgical mesh.

Refer to the recommended surgical technique guide for the GYNECARE PROLIFT™ Systems for further information on the pelvic floor repair procedure. Contact your company sales representative to obtain this surgical technique guide.

The safety and effectiveness of the GYNECARE PROLIFT™ Systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the GYNECARE PROLIFT™ Systems to synthetic mesh with the same indication has been demonstrated through benchtop and cadaveric testing. Information on the clinical performance of mesh for pelvic floor repair is available in published literature. Contact your company sales representative for assistance.

INDICATIONS

The GYNECARE PROLIFT™ Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

- GYNECARE GYNEMESH™ PS Mesh should not be used in infants, children, pregnant women, or women planning future pregnancies, as the mesh will not stretch significantly as the patient grows.
- GYNECARE GYNEMESH™ PS Mesh must always be separated from the abdominal cavity by peritoneum.
- GYNECARE GYNEMESH™ PS Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.
- The GYNECARE PROLIFT™ Systems should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.

WARNINGS

- Patients on anticoagulation agents undergoing surgery using the GYNECARE PROLIFT™ System must have their anticoagulation therapy carefully managed.
- Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.
- A digital rectal exam should be performed to detect possible rectal perforation.
- Cystoscopy may be performed to confirm bladder and ureteral integrity.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Use the GYNECARE PROLIFT™ Systems with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and to avoid vaginal wall perforation. Correct use of the GYNECARE PROLIFT™ Systems components will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.

PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT™ Systems.
- Avoid placing excessive tension on the mesh implant during placement.
- Do not manipulate the GYNECARE PROLIFT™ Retrieval Device with sharp instruments or cut it to alter its length.
- Do not affix the GYNECARE GYNEMESH™ PS Mesh Implant with any staples, clips, or clamps as mechanical damage to the mesh may occur.
- This product should only be used under the prescription of a physician.

- In patients with compromised immune systems or other conditions that would compromise healing the risks and benefits should be carefully weighed.
- Vaginal or urinary tract infection should be treated and alleviated prior to implantation.
- Acceptable surgical practice should be followed for the GYNECARE PROLIFT™ Systems as well as for the management of infected or contaminated wounds. If the Mesh Implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.
- Prolapse repair may unmask pre-existing incontinence conditions.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.
- The use of this product with tissue adhesives is not recommended, as data are not currently available.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureteral obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.

CLINICAL PERFORMANCE

Randomized, controlled clinical evaluations of the GYNECARE PROLIFT™ System are underway, but at this time preliminary data are available from two early observational studies of transvaginal mesh that were initiated in 2004. These observational studies evaluated a pre-cut surgical mesh made of the same non-absorbable polypropylene as the mesh used in the GYNECARE PROLIFT™ System. For these studies, the mesh was provided in shape similar to that of the GYNECARE PROLIFT™ System, though implantation instruments were not provided in these studies. One of the two studies involved eight investigational centers in France; the second included three investigational centers in the US. The protocols were similar, where both studies were conducted to evaluate the usability of a pre-cut mesh for anterior, posterior, and vault prolapse in women with symptomatic prolapse of at least ICS Stage III using the pre-cut mesh and a transvaginal surgical technique.

The inclusion criteria for both studies were as follows: symptomatic prolapse of at least ICS Stage III, subjects at least 21 years of age, subjects do not wish to become pregnant in the future, no uncontrolled diabetes, and no coagulation disorder. In the French study, an additional inclusion criterion was a prior or concurrent hysterectomy. The primary effectiveness endpoint for both studies was the proportion of subjects for whom correction of prolapse was achieved (ICS Stage 0 or I) evaluated at 12 months post-operatively. Secondary endpoints for both studies included: vaginal prolapse occurring in the area not treated with mesh, peri-operative complications, patient tolerance of synthetic mesh, post-operative complications, and quality of life (QOL). An additional secondary endpoint for the US study was the recurrence rate of vaginal prolapse in the area treated with mesh. Study populations available for follow-up at 12 months were 83 patients in the US and 87 patients in France with a median patient age of 62 and 66.5, respectively.

The 12-month postoperative study results were as follows (US, France): proportion of subjects with ICS Stage II or greater (12.0%, 18.4%), met pre-defined criteria of upper limit of 90% CI less than 20% (yes, no), Prolapse Symptom Index (PSI) mean (6.6, 3.1), Mean QOL score (0.7, 0.4).

Adverse events, expressed as percentages, were as follows (US, France): hematoma (3.5, 4.5), abscess (0, 1.1), urinary tract infection within 6 weeks post-procedure (8.2, 16.9), mesh exposure (14.1, 10.0), surgical intervention for mesh exposure (7.1, 5.6), vesico-vaginal fistula (1.2, 1.1), recto vaginal fistula (1.0, 0), moderate/severe vaginal retraction (3.6, 12.6).

More recent data specific to the GYNECARE PROLIFT™ System may be available in the published literature. Please contact your sales representative for more information.

DESCRIPTION

The GYNECARE PROLIFT™ Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNEMESH™ PS Nonabsorbable PROLENE® Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannules
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT™ Pelvic Floor Repair System Components